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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,013	02/09/2004	Jean-Marc Roch	1600.24	2028

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EXAMINER	
CHERNYSHEV, OLGA N	
ART UNIT	**PAPER NUMBER**
1649	

DATE MAILED: 08/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/776,013	ROCH ET AL.	
	Examiner	Art Unit	
	Olga N. Chernyshev	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 July 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *6-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/13/6*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Claims 1, 2, 3, and 20 have been amended as requested in the amendment filed on July 21, 2006. Following the amendment, claims 1 to 20 are pending in the instant application.

Claims 6-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on January 20, 2006.

Claims 1-5 and 20 are under examination in the instant office action.

2. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

4. Applicant's arguments filed on July 21, 2006 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Sequence compliance

5. This application remains non-compliant with the rules specifically articulated in 37 C.F.R. § 1.821 through 1.825 for those reasons of record in section 2 of Paper mailed on February 24, 2006. In response, Applicant refers to MPEP § 2422.02 and provides a partial quotation of relevant passage (p.6 of the Response). However, the full section of MPEP § 2422.02 states that

"In view of the fact that many significant sequence characteristics may only be demonstrated by a figure, the exclusive conformance requirement of this section may be relaxed for drawing figures. This is especially true in view of the fact that the representation of double stranded nucleotides is not permitted in the "Sequence Listing" and many significant nucleotide features, such as "sticky ends" and the like, will only be shown effectively by reference to a drawing figure. Further, the similarity or homology between/among sequences can only be depicted in an effective manner in a drawing figure. Similarly, drawing figures are recommended for use with amino acid sequences to depict structural features of the corresponding protein, such as finger regions and Kringle regions. The situations discussed herein are given by way of example only and there may be many other reasons for relaxing the requirements of this section for the drawing figures. It should be noted, though, that when a sequence is presented in a drawing, regardless of the format or the manner of presentation of that sequence in the drawing, the sequence must still be included in the Sequence Listing and the sequence identifier ("SEQ ID NO:X") must be used, either in the drawing or in the Brief Description of the Drawings", emphasis added. Thus, in accordance with MPEP § 2422.02, Applicant is required to comply with the Sequence rules for proper disclosure of sequences.

Claim Rejections - 35 USC § 101

6. Claims 1-5 and 20, as amended, stand rejected under 35 U.S.C. 101 because the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial credible utility for those reasons of record in section 5 of Paper mailed on February 24, 2006. Briefly, the instant application has provided description of focal adhesion kinase 2 (FAK2) and binding

experiments involving FAK2. The instant application does not disclose specific significance of biological activity of FAK2 with respect to treatment of Alzheimer's disease.

Applicant traverses the rejection on premises that the instant claimed method has relevance and utility with respect to treatment of Alzheimer's disease because (1) "changes in amyloid precursor metabolism are associated with Alzheimer's disease and neuronal death associated with Alzheimer's diseases" (middle at p.8 of the Response); (2) "inhibition of FAK2, or reduction in its expression, will result in decreased amount of $A\beta_{42}$ being secreted" (top at p. 9); Declaration of Dr. Bartel ("Bartel Declaration") "provides clear support for the credibility of the asserted "real world" use for the claimed method of identifying agents useful for the treatment of Alzheimer's disease (p.9). Applicant's arguments have been fully considered but are not persuasive for the following reasons.

The instant claims, as amended, are drawn to a method of selecting agents that are useful ("potentially useful", see last section of claim1, as currently presented) for the treatment of Alzheimer's disease (AD) by identifying test agents that inhibit the biological activity of FAK2. As fully explained in the previous office action of record, the instant specification fails to provide any factual evidence or sound scientific reasoning that would support a conclusion that the FAK2 is specifically associated with Alzheimer's disease or any other "neurological disorders, ailments and diseases". Characterization of FAK2 as being associated with Aβ production within experimental *in vitro* system, is clearly not sufficient to establish specific role of FAK2 in etiology or pathogenesis of Alzheimer's diseases, which would support the asserted utility of the instant claimed method for selecting pharmacological agents to treat Alzheimer's disease. The Examiner maintains that because the instant specification fails to establish that the

identification of a test agent as being capable to affect the activity of FAK2 would have suggested its specific use for the treatment of Alzheimer's disease, or any other basis for patentable utility, to a person skilled in the art at the time the application was filed, then significant further research would have to be performed substantiate the specific, substantial and credible utility of the instant claimed method.

The Declaration of Bartel under 37 CFR 1.132 filed July 21, 2006 is insufficient to overcome the rejection of claims 1-5 and 20 based upon §§ 101 and 112 as set forth in the last Office action for the following reasons.

The Declaration describes experimental data, which show that "overexpression of [...] FAK2 results in a statistically significant increase in Aβ40 and Aβ42 being secreted from human cells in culture" and further that "overexpression of [...] mutant FAK2 results in a statistically significant decrease in Aβ40 and Aβ42 being secreted from human cells in culture". Based on these results, Dr Bartel makes a conclusion that inhibition of FAK2 would lower production of Aβ, which in turn would lead to reduction of amyloid plaque formation in brains of Alzheimer's disease patients. First, it is noted that there appears to be total absence of data that would show that "inhibition" of FAK2 by an agent leads to reduction in Aβ production. Additionally, there appears to be no reference to any scientific publications in the filed that would support a conclusion that the instant described *in vitro* cell-based assay represents an art-accepted model of Alzheimer's disease. Regarding the merit of the argument, there appears to be clear established nexus that any agent that inhibits biological activity of FAK2, wherein such biological activity is (1) ability to bind proteins, (2) FAK2 catalytic activity, or (3) the ability to phosphorylate specific amino acid residues of FAK2, would be useful in inhibiting production of

amyloidogenic form of Aβ and, most importantly, would be useful in treatment of Alzheimer's disease. Thus, it appears that the Declaration provides only Dr. Bartel's own conclusions (as to what was done, and what it means) and no references to scientific reasoning or any evidentiary support (see *Meitzner v. Mindick,* 549 F.2d. 775, 782, 193 USPQ 17, 22 (CCPA 1977), "Argument of counsel cannot take the place of evidence lacking in the record").

The Court in *Brenner v. Manson* held that "[t]he basic *pro quid quo* contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point – where specific benefit exists in currently available form – there is insufficient justification for permitting an applicant to engross what may prove to be a broad field." Id. at 534-35, 148 USPQ at 695.

Thus, the basis *quid pro quo* of the patent system is the grant of a valuable legal right in exchange for a meaningful disclosure of the claimed invention. In the instant case, the disclosure of a method to select an agent potentially useful for treatment of Alzheimer's disease without disclosure of meaningful interpretation of the relevance of the claimed method to Alzheimer's pathology, does not entitle Applicants to the legal right they claim to exclude others from practicing the claimed invention.

Thus, for reasons explained in the previous office action s and reasons above, the instant rejection is maintained.

Claim Rejections - 35 USC § 112

7. Claims 1-5 and 20 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a clear asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

New grounds of rejection necessitated by amendment

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-5 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claim 1, as amended, is vague and ambiguous for recitation of structural characteristics of a polypeptide, such as "full-length focal adhesion kinase 2", 75% identity to FAK2", "fragments" and "phosphorylation of specific amino acid residues", without any reference to its specific amino acid sequence identified by SEQ ID NO. The metes and bounds of such recitations cannot be positively identified. Clarification is required.

11. Claim 1, as amended, is indefinite as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: "a second protein" recited in section (1), which role with respect to practicing the steps of the claimed method cannot be determined from the claim or the instant specification.

Furthermore, because it is not obvious if "second protein" is an element of the claimed method, recitation of "a first protein" is vague and ambiguous.

12. Further, Claim 1 is indefinite for being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: it appears that "comparing the difference in the measured biological activity in the presence and absence of said agent" is impossible because there are no steps where the test agent is absent. It is not clear and cannot be determined from the claim as how to measure biological activity of FAK2 in the absence of an agent when the activity is limited to binding an agent or a protein.

Applicant is advised to rewrite the claim to better express the claimed subject matter.

13. Claim 2 is vague and ambiguous for references to specific residues within the sequence of a polypeptide, which is not properly identified, see reasoning in section 10 of the instant office action.

14. Claim 3 recites the limitation "cells or tissues" in claim 1. There is insufficient antecedent basis for this limitation in the claim. Further claim 3 misses the steps of recited determination of Aβ production.

15. Claim 4 recites the limitation "cell expression focal adhesion kinase 2" in claim 1. There is insufficient antecedent basis for this limitation in the claim. Applicant is advised that contacting an agent with FAK2 or with a cell expressing FAK2 clearly represents two different method steps.

16. Claim 5 misses the critical steps, which disclose determination of levels of Aβ production.

17. Claim 20, as amended, does not make sense. Because the place of "a second protein" within the steps of the method of claim 1 is not obvious, it appears that the method encompasses binding of FAK2 as a first to FAK2 as a second protein. Clarification is required.

Conclusion

18. No claim is allowed.

19. This application contains claims 6-19 drawn to an invention nonelected with traverse in Paper filed on January 20, 2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Olga N. Chernyshev, Ph.D.
Primary Examiner
Art Unit 1649

August 28, 2006